

Patent Application  
Attorney Docket NO. PC11724H US

REMARKS

Director Elliott, Examiner Woodward and Examiner Peselev are thanked for graciously held an interview with Dr. Tim Creagan, Dr. Quallich and the undersigned on September 13, 2005. The present application and Singer et al., U.S. Patent No. 6,365,574 and its reissue application (hereinafter "Singer") were discussed. It was agreed that claim 87 and its dependent claims would be patentable over Singer based upon the Rule 132 declaration of George Quallich filed with the USPTO on September 12, 2005, if claim 87 is amended to limit the total amount of azithromycin dihydrate and the impurities in the substantially pure azithromycin monohydrate hemi-ethanol solvate to no more than 20% by weight.

Applicants have amended claim 87 to clarify that the substantially pure azithromycin monohydrate hemi-ethanol solvate in the claimed azithromycin mixture contains less than 10% of alternative polymorphic or isomorphous crystalline forms of azithromycin by weight and that the claimed azithromycin mixture optionally contains less than 10% of azithromycin dihydrate by weight.

Applicants further introduced new claims 133-136 to further define the purity of substantially pure azithromycin monohydrate hemi-ethanol solvate and the content of the optional azithromycin dihydrate in the claimed azithromycin mixture.

Support for the amendments to claim 87 and to new claims 133-136 can be found, *inter alia*, on page 2, lines 22-24 and on page 5, lines 13-29. Applicants respectfully submit that the present Supplemental Response and Amendment is fully supported by the original specification and does not raise any issue of new matter. Therefore, entry of the present Supplemental Response and Amendment is respectfully requested. Upon entry of the present Supplemental Response and Amendment, claims 87 and 126-136 will be under examination.

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CONCLUSION

In view of interview, the claim amendments and the remarks, further and favorable considerations of the presently pending claims and the issuance of a Notice of Allowance with regard to all pending claims are respectfully requested.

It is believed that no fee is required in connection with the present Amendment. However, if any fees are required, the Commissioner is authorized to charge such fees to our Deposit Account No. 16-1445.

Respectfully submitted,

Date: 09/14/05

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